

REMARKS

Claims 5, 7, and 13 are pending in the above-identified application. In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Drawings

Since no objection has been received, Applicants assume that the drawings are acceptable and that no further action is necessary. Confirmation thereof is respectfully requested.

Issues under 35 U.S.C. § 103(a)

Claims 5, 7, and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ueda et al. '103 (US 6,831,103) in view of Hamilton (J. Neurol. Neurosurg Psychiat, 1960, 23, 56). Applicants respectfully traverse. Reconsideration and withdrawal of this rejection are respectfully requested based on the following considerations.

Legal Standard for Determining Prima Facie Obviousness

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

- (a) determining the scope and content of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating any evidence of secondary considerations.

Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. See MPEP 2143.03.

The Present Invention

Independent claim 5 recites:

A method for treating an individual with a mood disorder having at least symptoms of feelings of guilt, suicide, and retardation:psychomotor, each symptom being assessed according to the assessment method by the Hamilton scale, comprising

administering an effective amount of a composition comprising theanine to the individual with the mood disorder in need of treatment,

wherein said mood disorder is distinct from mood disorders associated with menstruation; and

wherein said individual is a normofolatememic patient.

Distinctions over the Cited References

On page 4 of the outstanding Office Action, the Examiner asserts:

Ueda et al. does not specify that the symptoms of mood disorder as feelings of guilt, suicide and retardation:psychomotor; however, Ueda et al. generally teaches treating symptoms of mood disorder which would include all of these symptoms. Primarily anxiogenic symptoms are often indicated in feelings of guilt and suicide. Further diminished homeostasis symptoms read on the symptoms of retardation:psychomotor. Accordingly, Ueda et al. teaches treating mood symptoms which render the present invention obvious.

Applicants respectfully traverse. Specifically, a mood disorder having at least symptoms of feelings of guilt, suicide, and retardation:psychomotor in the present invention is essentially different symptoms from the anxiogenic symptoms in Ueda et al. '103. The mood disorder in the present invention has symptoms similar to depression. In contrast, as noted at column 4, lines 41-61 of Ueda et al. '103, the anxiogenic symptoms in Ueda et al. '103 are due to continuous or habitual intake of a methylxanthine derivative such as caffeine or an unidentified cause. That is, Ueda et al. '103 relate to suppression of increased anxiety in daily life and not to feelings of guilt or suicide. Test Example 3 in Ueda et al. '103 discloses the suppressive effect of the anxiogenic symptoms. In this test, however, the people tested are healthy and not patients. Thus, Ueda et al. '103 merely disclose the effect that a healthy person having a high level of anxiety is treated to lower the level of anxiety.

Also, the Examiner asserts that diminished homeostasis symptoms read on the symptoms of retardation:psychomotor. Applicants respectfully traverse and request that the Examiner provide some basis for this assertion. Although various symptoms would be caused due to diminished homeostasis, retardation:psychomotor would not have a direct relationship. Furthermore, the present invention relates to mood disorder rather than anxiety.

On page 2 of the outstanding Office Action, the Examiner asserts:

It is noted that Ueda et al. does not teach that the patient is having a lack of folate; therefore, absent a teaching that there is a deficiency in folate one would assume that the patient is a normofolatemetic patient. Further, Applicants have made a statement that the invention exhibits unexpectedly significant amelioration in the symptoms of normofolatemetic patients and this is an unexpected and unpredictable result; however, there is no showing of the criticality of the asserted unexpected result.

Applicants respectfully traverse. Ueda et al. '103 do disclose that the person has a lack of folate. Specifically, Ueda et al. '103 state:

Although a wide variety of causes are involved in the pathogenesis of these diseases, it is a key to their prevention and treatment to improve our dietary life. In other words, imbalanced nutrient intake also contributes to the development of the aforementioned diseases, despite the recent enrichment of our dietary life. Nutrition surveys have demonstrated that the minimum requirements are not satisfied for some minerals. Against this background, minerals have recently been added to foods, beverages, supplements, nutrition enhancers, and the like; however, their peculiar metal tastes limit the amount of their addition or reduce their commercial value (col. 1, lines 40-52; emphasis added).

Thus, Ueda et al. '103 actually disclose a connection between a person with a lack of folate and various diseases. Therefore, Ueda et al. '103 do not disclose a normofolatemetic patient. Aside from Test Example 3 of Ueda et al. '103, the symptoms of Ueda et al. '103 are derived from imbalanced nutrient intake so that folate levels would not be normal.

In contrast, the subject individuals in the present invention are patients of mood disorder and not healthy persons. In this regard, subject individuals in the present invention are normofolatemetic patients. Here, since patients are normofolatemetic, the nutrient intake for the patients is well-balanced, and their dietary habits are normal. Thus, since the folate level is normal in the patients of the present invention, the pending claims are never suggested by the general disclosure relating to diminished homeostasis in Ueda et al. '103.

To establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be disclosed by the cited references. As discussed above, Ueda et al. '103 in view of Hamilton fail to disclose all of the claim limitations of independent claim 5, and those claims dependent thereon. Accordingly, the combination of references does not render the present invention obvious.

Furthermore, the cited references or the knowledge in the art provide no reason or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed. Therefore, a *prima facie* case of obviousness has not been established, and withdrawal of the outstanding rejection is respectfully requested. Any contentions of the USPTO to the contrary must be reconsidered at present.

Conclusion


All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Chad M. Rink, Registration No. 58,258, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: November 4, 2010

Respectfully submitted,

By 

Craig A. McRobbie
Registration No.: 42,874
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road, Suite 100 East
P.O. Box 747
Falls Church, VA 22040-0747
703-205-8000